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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 30 August 2002 with an application for Letters Patent number 521107 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 10 September 2003.

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

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PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Humidification System"

We, FISHER & PAYKEL HEALTHCARE LIMITED, a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a humidification system, particularly but not solely, for supplying optimal humidity temperature of gases to a patient to assist the patient's breathing for ventilation purposes, or for the supply of gases for other medical procedures, such as laparoscopic, endoscopic or ophthalmic procedures.

Summary of the Prior Art

A number of methods are known in the art for assisting a patient's breathing. Continuous Positive Airway pressure or CPAP involves the administration of air under pressure to a patient, usually by a nasal mask. It is used in the treatment of snoring and Obstructive Sleep Apnea (OSA), a condition characterised by repetitive collapse of the upper airway during inspiration. Positive pressure splints the upper airway open, preventing its collapse. Treatment of OSA with nasal CPAP has proven to be both effective and safe, but CPAP is difficult to use and the majority of patients experience significant side effects, particularly in the early stages of treatment.

Upper airway symptoms adversely affect treatment with CPAP. Mucosal drying is uncomfortable and may awaken patients during the night. Rebound nasal congestion commonly occurs during the following day, simulating a viral infection. If untreated, upper airway symptoms adversely affect rates of CPAP use.

Increases in nasal resistance may affect the level of CPAP treatment delivered to the pharynx, and reduce the effectiveness of treatment. An individual pressure is determined for each patient using CPAP and this pressure is set at the mask. Changes in nasal resistance affect pressure delivered to the pharynx and if the changes are of sufficient magnitude there may be recurrence of snoring or airway collapse.

Such symptoms can also occur in a hospital environment where a patient is on a respirator. Typically in such situations the patient is intubated. Therefore the throat tissue may become irritated and inflamed causing both distress to the patient and possible further respiratory problems.

A number of methods may be employed to treat such upper airway symptoms, including pharmacological agents to reduce nasal disease, or heating the bedroom. One most commonly employed method is humidification of the inspired air using an in

line humidifier. Two types of humidifier are currently used. Cold pass-over humidifiers rely on humidifying the air through exposure to a large surface area of water. While they are cheap, the humidity output is low at high flows, typically 2 to 4 mg\L absolute humidity at flows above 25L/min. The output is insufficient to prevent mucosal drying. Heated water bath humidifiers are more efficient, and produce high levels of humidity even at high flow rates. They are effective at preventing upper airway mucosal drying, prevent increases in nasal resistance, and are the most reliable means of treating upper airway symptoms.

Any of these active systems will have, to some degree or other, condensation (or rain out) in the tubing connecting the humidifier to the patient. The degree of condensation is strongly dependent on the ambient temperature, being much greater for greater differences between the ambient temperature and the gas temperature. The formation of large quantities of water in the breathing tubing causes considerable inconvenience to the patient, may accelerate cooling of the gas, may eventually occlude the tubing, or may be expelled into the patient. Also, the patient may experience discomfort, when breathing gases are delivered at temperatures widely divergent from that of the ambient temperature. Excessive condensation also results in inefficient usage of the water in the humidifying chamber.

In a hospital environment, where the ambient temperature of the atmosphere within the hospital environment is controlled by air conditioning for example, the required temperature for the humidified gases supplied by the apparatus may be controlled within set temperature parameters that are sufficiently close to the ambient temperature to prevent condensation within the conduit. However it is still necessary to have good control over the temperature and humidity of gases as they are actually supplied to the patient.

In the home care environment in which a user requires to use humidifying apparatus at home, the range of ambient and gas temperatures may well exceed that of the hospital environment. In the home care environment, the user will usually wear a facemask that is connected to end of the conduit and such a humidifier may be used in the home environment for the treatment of breathing and sleep apnea disorders and/or

in conjunction with ventilators or CPAP devices. In addition, non-active humidifiers are commonly employed utilising the known pass over humidification technique.

For medical procedures where a patient's cavity is inflated for surgery, such as with laparoscopic or endoscopic surgery, it is important that gases entering the cavity are humid and at body temperature so as not to cause drying of the cavity tissues and to improve the recovery time of the patient.

In US Patent No. 5640951 issued to Fisher and Paykel a heated conduit for a humidified breathing assistance apparatus is disclosed which includes a temperature probe at the end of a heated conduit. By heating the conduit the problems relating to condensation in the conduit may be overcome. However in order to implement closed loop control over the temperature of the supplied gases (and therefore the power input to the conduit heating element 21), it is necessary to measure the temperature as close to the point at which it is supplied as possible. The temperature probe and its associated wiring included for this purpose make the attachment to the facemask or intubated patient bulky and therefore more uncomfortable for the patient. Also for other medical procedures the probes and associated wiring also result in bulky attachments at the operation entry point causing obstructions to the surgeon or pressure sores around the point of entry.

WO01/13981 of Fisher & Paykel Healthcare Limited discloses a breathing assistance apparatus adapted to deliver humidified gases at a desired level of humidity to a patient, including a humidifier and a heated conduit. The humidifier includes a controller, which determines a parameter of gas flow rate and then the required power input to the humidifier to deliver the gases to the patient at the required patient humidity. In a second embodiment, a conduit heating element is provided and the controller determines whether it has been correctly connected to the control. The heater plate of the humidifier is controlled to a particular temperature (set point) or the heater plate power is controlled through estimation or measurement of flow and/or ambient temperature. The heating element within the conduit is controlled by controlling the power to the heater through measurement or estimation of flow and ambient temperature. This eliminates the need for probes or external sensors. The blower or fan of this apparatus is pressure controlled for the purpose of treating CPAP.

With this system the humidity of the gases supplied to the patient is not so accurate, particularly at high flows.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a breathing assistance apparatus which goes some way to overcoming the abovementioned disadvantages or which at least provides the public or industry with a useful choice.

Accordingly in a first aspect the invention consists in a humidification system adapted to deliver humidified gases at a desired level of humidity, flow and temperature to a patient comprising:

a) gases supply means providing a flow of gases,

b) humidification means having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient,

c) flow measuring means that determines the flow of said gases before entry of said gases to said humidification means,

d) humidity sensing means measuring the humidity of said gases before entry of said gases to said humidification means,

e) first temperature sensing means measuring the temperature of the air external to said humidification system,

f) transportation pathway means, having a heating means, said pathway means conveying said humidified gases from said humidification means to said patient, and

g) control means including stored instructions to:

i) determine a transportation pathway heating means input power based on at least said temperature of said air as measured by said first temperature sensing means and said flow of said gases as measured by said flow measuring means,

ii) determine a humidification means input power based on at least said flow of said gases as measured by said flow measuring means and said humidity of said gases as measured by said humidity sensing means,

to achieve said desired humidity, flow and temperature of said gases, which are to be supplied to said patient.

Preferably said humidification means comprises a humidification chamber adapted to receive a volume of water and water heating means to heat said water, said

gases passing through said humidification chamber, through a gases inlet and out a gases outlet, and evaporating said water, said gases thereby being humidified.

Preferably said humidification system includes a second temperature sensing means measuring the temperature of said water heating means.

In a further aspect the invention consists in a humidification system adapted to deliver humidified gases at a desired level of humidity, flow and temperature to a patient comprising:

a) gases supply means providing a flow of gases,

b) humidification means having an electrical input power and capable of humidifying said gases up to a level of humidity prior to delivery to said patient,

c) flow measuring means measuring the flow of said gases before entry of said gases to said humidification means,

d) humidity sensing means measuring the humidity of said gases before entry of said gases to said humidification means,

e) first temperature sensing means measuring the temperature of the air external to said humidification system,

f) second temperature sensing means measuring the temperature of said water heating means,

g) transportation pathway means, having a heating means, said pathway means conveying said humidified gases from said humidification means to said patient, and

h) control means including stored instructions to:

i) determine a transportation pathway heating means input power based on at least said temperature of said air as measured by said first temperature sensing means and said flow of said gases as measured by said flow measuring means,

ii) determine a required temperature of said water heating means based on at least said flow of said gases as measured by said flow measuring means and said humidity of said gases as measured by said humidity sensing means,

iii) determine the actual temperature of said water heating means from said second temperature sensing means,

iv) vary input power of said water heating means to cause said actual temperature to approach said required temperature,

to achieve said desired humidity, flow and temperature of said gases, which are to be supplied to said patient.

Preferably said humidification system includes a third temperature sensing means measuring the temperature of the gases before entry of said gases to said humidification means.

Preferably said control means further includes instructions to determine said humidification means input power based on said flow of said gases as measured by said flow measuring means, said humidity of said gases as measured by said humidity sensing means, and said temperature of said gases as measured by said third temperature sensing means.

Preferably said humidification system includes pressure sensing means measuring the pressure of said gases before entry of said gases to said humidification means.

Preferably said control means further includes instructions to determine said humidification means input power based on said flow of said gases as measured by said flow measuring means, said humidity of said gases as measured by said humidity sensing means, said temperature of said gases as measured by said third temperature sensing means and said pressure of said gases as measured by said pressure sensing means.

Preferably said humidification system includes an additional gases input port and at least one oxygen sensing means located in said flow of gases to measure said gases oxygen concentration.

Preferably said additional gases input port allows for the addition of oxygen to said flow of gases through said humidification system.

Preferably said control means further includes instructions to determine said humidification means input power based on said flow of said gases as measured by said flow measuring means, said humidity of said gases as measured by said humidity sensing means, said temperature of said gases as measured by said third temperature sensing means and said oxygen concentration of said gases as measured by said oxygen sensing means.

Preferably said gases supply means, humidification means, flow measuring means, humidity sensing means, temperature sensing means, pressure sensing means and control means are housed in one housing so that there are no external sensors and wiring on said humidification system to hinder said patient or other user of said humidification system.

Preferably said housing has an external inlet for gases into said gases supply means and an outlet for said humidified gases, where said outlet is from said humidification chamber which is connected to said transportation pathway means by way of a connector that provides both an electrical and pneumatic connection between said humidification chamber and said transportation pathway.

Preferably said humidification system includes transportation pathway means overheating detection for said heating means comprising:

detecting means which include means to detect a current in said heating means, and

detection control means which stores a program which causes the control means to:

i) receive input of said current in said heating means from said detecting means, and

ii) if said current is below a safe current value, then reduce the power to said heating element from a operating current value to at least said safe current value, else return to i),

iii) increase the power to said heating element after a predetermined time to said operating current value.

Preferably said transportation pathway means is an extruded plastic tube, and said heating means is at least two conductive wires embedded within the wall of said tube to be partially or wholly contained within said wall.

Preferably the cross sectional profile of said extruded plastic tube is such that total collapse or total occlusion is not possible during bending. For example the tube may include inwardly extending ribs on its inner surface.

Preferably said extruded plastic tube includes two or more co-extruded layers of differing plastic materials with varying properties.

Preferably said wire is a positive temperature co-efficient heating element, for example in a wire or tape form.

Preferably said humidification chamber includes a float valve system for controlling the level of liquid in a chamber comprising:

a valve body having an inlet for coupling to a liquid supply conduit and an outlet adapted to communicate with said chamber,

a first valve seat formed in said body through which liquid must pass to reach said outlet,

a second valve seat formed in said body located downstream of said first valve seat, through which liquid must pass to reach said outlet,

first and second floats adapted to be disposed within said chamber,

a first valve member actuated by said first float so as to close onto said first valve seat upon the first float assuming a position corresponding to a first predetermined level of liquid in said chamber,

a second valve member actuated by said second float so as to close onto said second valve seat upon the second float assuming a position corresponding to a second predetermined level of liquid in said chamber, said second predetermined level of liquid being higher than said first predetermined level of liquid,

a cylindrical actuating member connected to said second valve member in order to control displacement of said second valve member in response to said second float,

an inner actuating member connected to said first valve member in order to control displacement of said first valve member in response to said first float, said inner actuating member being disposed within said cylindrical actuating member,

said cylindrical actuating member and said inner actuating member independently connecting said first and second floats to respective valve members, and operable to allow free relative movement between said first and second valve members.

Preferably said gases supply means is a fan driven by a variable speed electric motor.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or

collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a schematic of the humidifier system of the present invention,

Figure 2 is detailed block diagram of the humidification system of the present invention,

Figure 3 is an illustration of the oxygen port of the humidification system of the present invention, and

Figure 4 is a perspective view of the humidification system of the present invention when housed in one housing.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Whether used in a hospital environment or in a home care environment, the humidification system of the present invention will generally have associated with it a gases supply, such as ambient air, gases from cylinders, other compressed gas supply or gases from an insufflator, and a transport conduit from the humidification system to the patient, which is preferably heated to reduce condensation, or "rain out".

A heating element is preferably provided within the conduit to help prevent condensation of the humidified gases within the conduit. Such condensation is due to the temperature of the walls of the conduit being close to the ambient temperature, (being the temperature of the surrounding atmosphere) which is usually lower than the temperature of the humidified gases within the conduit. The heating element effectively replaces the energy lost from the gases through conduction and convection during transit through the conduit. Thus the conduit heating element ensures the gases delivered are at an optimal temperature and humidity.

The humidification system of the present invention may be used for various applications such as laparoscopic, ophthalmic or other surgical procedures, tracheostomised patients, and trans-tracheal insufflation. The humidification system

of the present invention may be used in any treatments requiring or benefiting from the supply of a humidified gas supply.

The present invention provides a humidification system where the flow of gases passes in sequence through a flow driver (such as, a blower, fan, compressor or insufflator), humidification chamber and then heated delivery circuit. This system is contained such that the measurements made to control the flow, humidity and temperature of gases are internally sensed, so that there are no external sensors or electrical leads to components to hinder the patient or operator. This not only saves the cost of the extra sensors but also makes the system simpler and easier to set-up, operate and clean.

Typical blower humidifier combinations have been designed for the treatment of OSA and are pressure-controlled devices. They are also typically designed to be used as stand-alone blowers or in combination with a simple humidifier. These therefore typically deliver low levels of humidity i.e. 28 to 32mg/L. The present invention is intended to deliver body temperature saturated gases (37°C and 44mg/L for room air) over a range of flows that would typically be used to provide for a patient's inspiratory flow requirements (that is, peak inspiratory flow).

The humidification system operates as a pressure limited, flow controlled device, so it adjusts the flow of gases to the level set by the patient. Therefore, this system can be used to deliver humidified gas for patients with bypassed airways, such as tracheotomies or nasal cannula or masks or for other systems that require high flow gases. This has the potential to benefit many patients in both the home and hospital environments.

The humidification system of the present invention provides a much more accurate control of the delivered gas condition through estimation or measurement of any combination of flow, humidity, temperature and pressure, prior to the humidification chamber, and by use of the sensed ambient temperature. A subsequent calculation of the required heating element power, heater plate temperature set point and/or heater plate power can then be made to achieve optimal humidity, temperature and flow. Clinical data exists to suggest that gases at 37°C and containing 44mg of

water vapour per litre at approximately atmospheric pressure are "optimal" for patient health.

The invention consists in a humidification system adapted to deliver humidified gases at a desired level of humidity, flow and temperature to a patient.

Referring to Figure 1, the flow of gases through the humidification system 1 passes from the air within a room, through the inlet 2 (that may also include a filter or the like) into the internal fan unit 3 (blower or the like) then may be mixed with an additional pressurised gas supply 8 at junction 9 and then flow into humidification chamber 4 via an inlet port 10. In the preferred form of the humidification system the additional gas supply is mixed with the gases from the fan, but in other forms of the present invention no additional gas supply is provided.

Beneath the humidification chamber is a heater plate 5, which heats water held within the chamber 4. The gases exit the chamber 4 and pass out from the humidification system 1 to a heated delivery circuit 6 and to a patient (not shown). A controller (not shown) connects and controls all the components mentioned above and will be described in more detail below.

Referring to Figures 1 and 4, in the preferred embodiment the fan unit 3 and humidifier, including chamber 4 and heater plate 5, and various controllers of these, are housed in one housing 13 and sensors, which are used to monitor various internal parameters of the fan, humidifier and gases, are internal within the housing 13, except for the external gas ambient air temperature sensor (T_{amb}) 12 that extends out slightly from the housing 13 so as to enable sensing of the ambient air surrounding the gases inlet 2.

In the preferred embodiment the humidification chamber extends out from the housing as shown in Figure 4, and is capable in use of being removed and replaced by the patient or other user. Also, the inlet port 10 to the humidification chamber 4 is internal within the housing 13. The inlet 2 to the housing 13 where gases are drawn from the ambient air outside the housing 13 is located at the end of the housing 13, but in actuality may be located at any appropriate point in the housing 13. It must be appreciated that the embodiment described above in relation to the housing and Figure

4 merely illustrate one form of the housing of the humidification system of the present invention.

In the preferred form of the present invention the fan 3 or flow source used within the humidification system is an electrically powered fan. Furthermore, it is preferred that the humidification chamber 4 sits atop an electrically powered heater plate 5 and an electrically powered heating element resides within the delivery circuit 6. These embodiments have been used for explanation purposes only. Any other suitable embodiment could have the same control scheme applied to it; for example, the fan could be replaced by a compressor, the chamber by a heated aerosol generator and the heater by a warm water jacket.

In the embodiment of the present invention as shown in Figures 1 to 4, an orifice plate 7 is used as the flow sensor and pressure sensor. The orifice plate allows for the measuring of the pressure of the gases after the gases leave the fan. From these measurements the velocity (flow) of the gases can be calculated. However, it must be appreciated in other forms of the present invention, other flow sensing devices such as a venturi or hotwire anemometer could be used. Furthermore, in other embodiments the flow sensor and pressure sensors taking measurements after the fan may actually be separate sensors.

Controlling the Flow of Gases

The desired flow of gases to the patient is selected by the user from a set of discrete options, i.e. 20L/min or 40L/min and is termed "set flow". The user choice is limited to these options in order to simplify the humidity and temperature control of the humidification system. A continuous range of flow settings may not be clinically necessary and the discrete settings may encourage better and more standardised use of the system.

Referring again to Figure 1, a portion or all of the total flow of gases through the humidification system 1 passes from the surrounding air within a room through the inlet 2 (that may also include a filter or the like) into the internal fan unit 3. Preferably the internal fan unit 3 is an electric fan, which blows external surrounding air through the humidification system. A portion of the total flow may be supplied from an additional pressurised gas supply 8, which mixes with the air at junction 9. Preferably

the pressurised gas is oxygen, such that the air-oxygen mix delivered to the patient is rich in oxygen. Preferably the user is able to alter the concentration of oxygen.

Referring to Figures 1 and 2, in the preferred embodiment the flow of gases through the humidification system 1 is measured by sensing the pressure on both sides of an orifice plate 7 situated as shown in Figure 1 after the fan 3 outlet and orifice plate 7. The pressure on the fan 3 side of the orifice 7 is denoted P_f and the pressure on the down stream side is denoted P_{in}. This method of flow sensing is well known in the art and the orifice plate can be calibrated to give an accurate flow measurement, termed measured flow. The fan speed V_{fan} is then varied (by varying the power into the fan or the current to the fan I_{fan}) so that the measured flow of gases approaches the set flow as selected by the user.

Flow Sensor Checking

Correct operation of the flow sensor (orifice plate 7) can be monitored and checked by using less accurate flow estimation methods to find the operating flow range, if the flow sensor is outside of this range then the sensor is found to have failed. This improves safety and allows the device to be tolerant of some faults. The humidification system may be able to continue to operate or may cause an alarm to be signalled and the device to switch to a safe mode. The flow estimation method employed may be as described in WO 01/13981 of Fisher & Paykel Limited, the contents of which are herein incorporated, where the flow is estimated from the fan speed and the loading on the fan, or the flow can be estimated from the relationship between the sensed temperature of the heater plate and the power drawn by the heater plate.

Controlling the level of Humidity of Gases – Heater Plate Control

The desired level of humidity of gases as supplied to the patient is selected by the user from a set of discrete options, i.e. "High" or "Medium". Each humidity set point refers to an actual humidity output. Preferably the High option refers to a humidity level of fully saturated gas at body temperature. Alternatively the humidity level can be described as 44mg/L. Preferably the Medium option refers to a humidity level that is lower than the High option and both safe and comfortable to patients at the set flow for long periods.

Referring to Figures 1 and 2, the flow of gases through the humidification system 1 continues from the flow sensor 7, down a short conduit, past the temperature sensor and humidity sensor 16 into the humidifier chamber 4. The water within the humidification chamber 4 is in thermal contact with heater plate 5. The heating of the water directly affects the humidity output of the humidification chamber 4. Thus as the flow of gases pass out of the humidification chamber 4 exiting out the outlet port 11 the humidity level contained in the gases is affected by the electrical power input into the heating element (not shown) of the heater plate 5. Conversely, the humidity level contained within the gases is affected by the temperature of the water in the humidification chamber 4, or, as a result of, the temperature of the heater plate 5.

The humidity and flow of gases required to be delivered by the system to the patient is selected by the user, and thus the energy required to be delivered by the humidification means is known, as will be described below. The energy of the gases entering said humidification chamber 4 is also known from sensing flow, humidity and temperature by respectively using a flow sensor 14 (shown in Figure 1 as the orifice plate 7), humidity sensor 16 and temperature sensor 15 before the humidification chamber 4. The basis of the humidity control employed in this invention is conservation of energy. The energy entering into and energy exiting from the humidification chamber 4 is known, therefore using conservation of energy principles the energy required to be added by the heater plate to ensure the required energy exits the humidification chamber 4 can be calculated.

In the preferred form of the humidification system the humidification chamber has a water autofeed mechanism that ensures the volume of water within the humidification chamber remains constant at all times. Furthermore, this autofeed mechanism ensures that the heat capacity of the water remains constant, which further simplifies the complexity of control required of the humidifier. An humidification chamber with autofeed capabilities that is suitable for this application is described in US5445143 of Fisher & Paykel Limited, the entire contents of which is incorporated herein. In this autofeed chamber the water level within the chamber is maintained by the use of floats that actuate valves to control the passage of water through a water inlet. Two floats are each provided with actuating mechanisms to separately control

the respective valve members. The separate valve members are covered by an elastomeric moulding that couples the valve members and provides a seal. The valves are co-axially aligned and the system provides improved safety by allowing for reliable operation in the case where one of the floats fails.

The preferred form of the humidification system is designed to operate at flows of around 40 L/min and deliver up to 44mg/L of water vapour; this results in consumption of 106mL of water every hour. In order to achieve stable control the thermal inertia of the system must be low, this translates to a need to keep the chamber water volume small. The resulting specification of a low volume but high consumption humidification chamber necessitates an autofeed system. A manual feed chamber is inherently unstable as users add large volumes of cold water over a short period of time. This greatly affects the humidity output of the chamber.

The humidifier is in a very steady state with a constant flow of gases and small amounts of water steadily being added to a chamber with low thermal inertia. This steady state allows application of the steady flow energy equation. The amount of electrical power required to be supplied to the heater plate can be calculated as below.

$$\dot{Q}_{hp} = \dot{Q}_{out} - \dot{Q}_{in}$$

Where, $\dot{Q}_{out}$ is constant as specified by the user and $\dot{Q}_{in}$ is the enthalpy of the incoming gas stream, which is dependent upon the temperature and humidity of the incoming gas stream.

Therefore, $$\dot{Q}_{hp} = A + B \cdot H_{absolute} + C \cdot T_{in}$$

Where:

$\dot{Q}_{hp}$ = Heater plate power,

$\dot{Q}_{out}$ = Energy of gas passing out of chamber,

$\dot{Q}_{in}$ = Energy of gas passing into chamber,

$H_{absolute}$ = Absolute Humidity at inlet of humidification chamber,

T_{in} = Gas temperature at inlet of humidification chamber,

$A, B, C, D, E \& F$ = Constants found experimentally for a specific flow and output humidity level, and

T_{hp} = Heater plate temperature

Alternatively the heater plate set point temperature can be calculated using:

$$T_{hp} = D + E \cdot H_{absolute} + F \cdot T_{in}$$

In this equation the constants take account of the thermal resistances within this specific system and are found experimentally.

The user selects the desired flow and humidity options to be delivered, for example 40L/min & 44mg/L, the heater plate controller 17 uses the constants known for this combination of options (i.e. D = 96.37, E = -0.79, F = -0.22) and measures the temperature and humidity level of the gases coming into the humidification means (for example T_{in}= 35°C, $H_{absolute}$= 8.75mg/L) then the heater plate temperature set point is calculated as below.

$$T_{hp} = 96.37 - 0.79 \cdot H_{absolute} - 0.22 \cdot T_{in}$$

$$T_{hp} = 96.37 - 0.79 \times 8.75 - 0.22 \times 35$$

$$T_{hp} = 81.66\,°C$$

When there are gases at 35°C containing 8.75mg/L of water vapour, and these gases are flowing into the humidification chamber at 40L/min, the heater plate temperature set point is calculated to be 82°C. When the sensed heater plate temperature approaches its set point the humidity output from the chamber approaches 44mg/L.

It will be appreciated that a further embodiment of the invention could incorporate a sensor on the outlet of the humidification means to allow closed loop control as is known in the art. The novel concepts of the present invention could be incorporated to such a system to allow advances in the therapy. Many current humidifiers use temperature sensors or the like on the outlet, make an assumption that gases are close to saturated, and then control to a dry-bulb temperature set point. The assumption of saturation is incorrect for some inlet conditions, for example high inlet temperature or humidity, and this can cause the delivered absolute humidity to deviate widely from the desired or optimal level. This further embodiment of the present invention would operate under the common closed loop control method with the addition of a humidity sensor at the inlet of the humidification means. The information provided by such a sensor would allow an estimate of the correct dry-bulb

temperature set point necessary to achieve the desired level of absolute humidity. Calculation of this set point would be similar in method and principle to the calculation described above. This humidification system of this embodiment would be considerably more reliable in its delivery of saturated gases than currently available humidifiers.

Controlling Humidity and Temperature of Gases - Heated Delivery Circuit Control

As shown in Figures 1 and 2, the flow of gases exit the chamber 4 and pass out from the humidification system 1 to a heated delivery circuit 6 and to a patient 22. The heated delivery circuit 6 is a plastics conduit having a heated wire 21 extending through it, for example, such as that disclosed in any one of NZ516387, NZ514314 and NZ521017, all of Fisher & Paykel Healthcare Limited, the contents of which are incorporated herein. The delivery conduit has wires extruded within the tubing walls. The conduit is extruded from an appropriate plastics material, such as a flexible polymer. The conduit has ridges or ribs extending from the surface of the conduit wall. Each rib extends towards the centre of the conduit and has a heating element, usually a wire that is embedded along the conduit's length. The heater wires may be made from copper, copper alloy or other appropriate electricity conducting material, such as a PTC heater. The heater wire is embedded within the ribs of the conduit by co-extrusion at the time the polymer conduit is extruded.

The heated delivery circuit 6 controls the temperature of the gases received by the patient 22. Both the temperature of the gases delivered to the patient, and the temperature of the gases at any point within the conduit are controlled. In order to transport the humidified gases produced from the humidification chamber the gases must be kept above the dew point temperature at any point within the delivery circuit in order to be able to transport all of the water vapour and avoid condensate. Referring to Figure 2, the conduit heater controller 17 calculates the power required to be used to heat the delivery conduit 6 for a specific humidity setting and flow setting based off the ambient temperature T_{amb} of the room. This ambient temperature is measured by the temperature sensor 12 (see Figure 1) at the fan inlet 2 and enables the gauging of the amount of heat loss from the delivery conduit 6 to the surrounding ambient

conditions. The relationship between said ambient temperature and the power used to heat the delivery conduit 6 in order to achieve the desired temperature at the patient is found experimentally.

Oxygen Mixing

Referring to Figure 3, the humidification system of the present invention in the preferred form incorporates an external port for the mixing of additional gases, preferably oxygen, into the gases flow. The port 40 is connected to a pressurised oxygen source and thereby causes oxygen to be added to the gases flow through the humidification system at a point before the humidifier, but after the fan 3.

It is usual to use a blender to mix the air and oxygen, however this requires both a compressed oxygen and air supply which is commonly not available, a blender is also expensive and thus adds a large additional cost. The other common method of mixing air and oxygen is an air entrainer. An air entrainer operates by using a high velocity jet of oxygen to shear past surrounding room air, which draws in some of this surrounding air and creates a mixed flow of gases down stream. The main disadvantage of an air entrainer is that if the downstream conduit has a large resistance to flow then the air entrainer is unable to generate a driving pressure to overcome this, and thus can't generate a flow. As the preferred embodiment of the present invention includes a long flexible conduit to deliver the gases to the patient, an air entrainer will not function in this circumstance.

In the preferred embodiment of the humidification system to measure the oxygen concentration of the gases flowing through the system either an oximeter (not shown) is provided in the mixed gas stream in a similar location to that of 42 or three flow meters 41, 42, 43, one each on the inward flowing oxygen stream 41, gases flow from the fan 43 and mixed gases flow 42 are provided. Any one of these three sensors are redundant for safety, the total flow and oxygen concentration can be calculated from any two of these sensors and should any one of these sensors fail these quantities are still known. As oxygen can be toxic in high concentrations it is important that this measurement is correct. It is displayed on the unit and clinical decisions may be made from this information. In order to allow for flexibility of the volume inputted into the gases flow, at the oxygen port 40 a needle valve 44 with a volume control knob is

provided. This allows a user to alter the volume of the oxygen flow into the humidification system and ultimately the concentration of oxygen inspired by the patient.

Overheating Detection

The humidification system of the present invention includes within the conduit heater plate controller 18 a delivery conduit overheating detection system, such as that disclosed in NZ516387 of Fisher & Paykel Healthcare Limited, the contents of which are herein incorporated. Such a detection system for the heating element includes a method of detecting conduit overheating where, when the conduit is hot the current drawn by the heating element within the conduit exceeds a predetermined limit. The detection system ensures that the humidifier and conduit can be switched to a safe mode then back to an operating mode once the temperature of the heating element within the conduit has reduced to safe levels. The device comprises a sensor to detect the current in the heating element and controller that implements an algorithm to reduce the current in the heating element to a safe current region. If the conduit comprises two limbs the sensor detects the currents in each of the limbs determines the difference between these currents and if the difference approaches a predetermined limit then the power to each of the heating elements is reduced.

Electro Pneumatic Connector

In the preferred form of the humidification system of the present invention the delivery conduit 6 is connected to the output port 11 by way of an electro pneumatic connector, such as that described in NZ519374 of Fisher & Paykel Healthcare Limited, the contents of which is herein incorporated. In particular a connector of this type is utilised where the conduit has a heating element or electrical wire extending within, throughout and about it. The conduit is connected to the humidification chamber via a connector that provides both an electrical 19 and a pneumatic 20 coupling. In Figure 4, only the chamber 4 side of a single port electro pneumatic connector is shown. In this form the single port connector is generally tubular and has a male and female portion where the pneumatic coupling is by a threaded, sliding collar or bayonet type connection that has an integral electrical port that provides power to the wire in the conduit.

DATED THIS 30th DAY OF August 200
AJ PARK
PER
AGENTS FOR THE APPLICANT

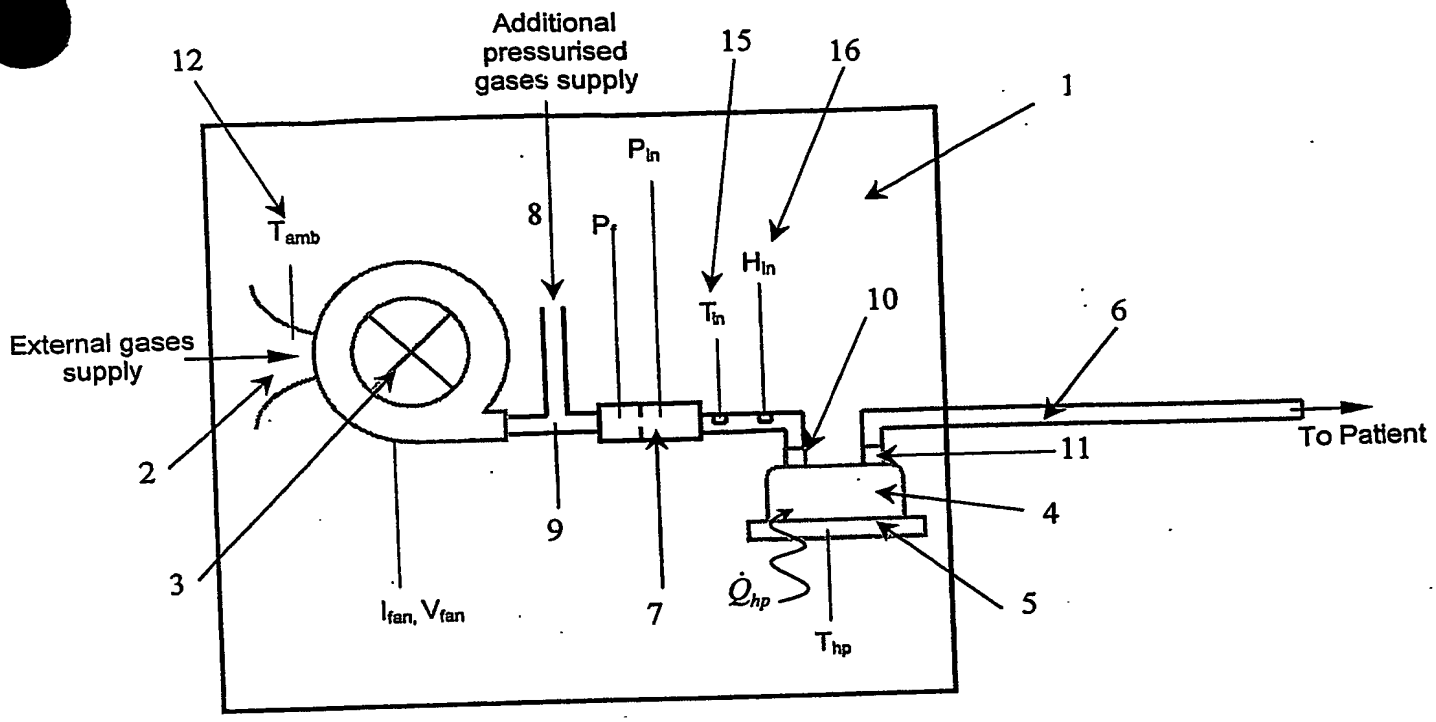

Figure 1

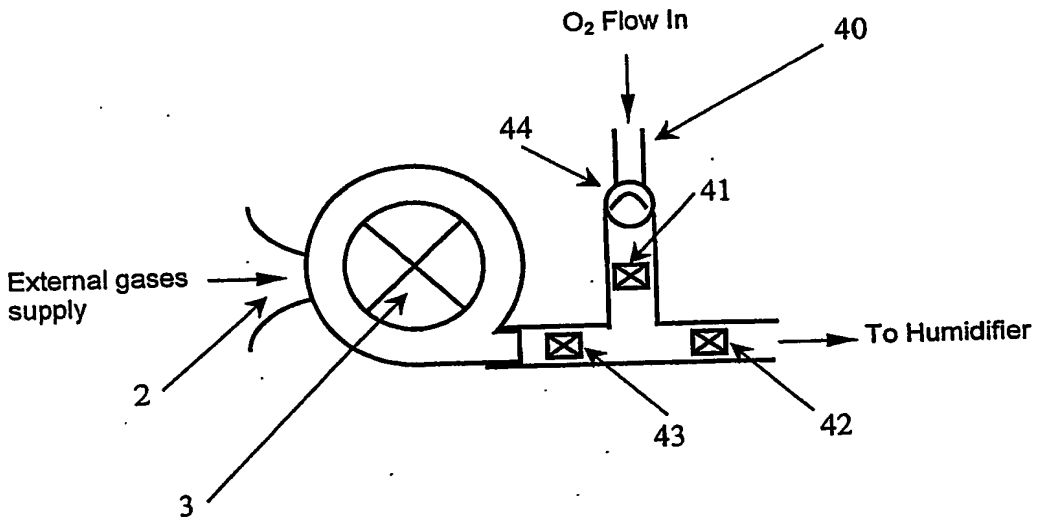

Figure 3

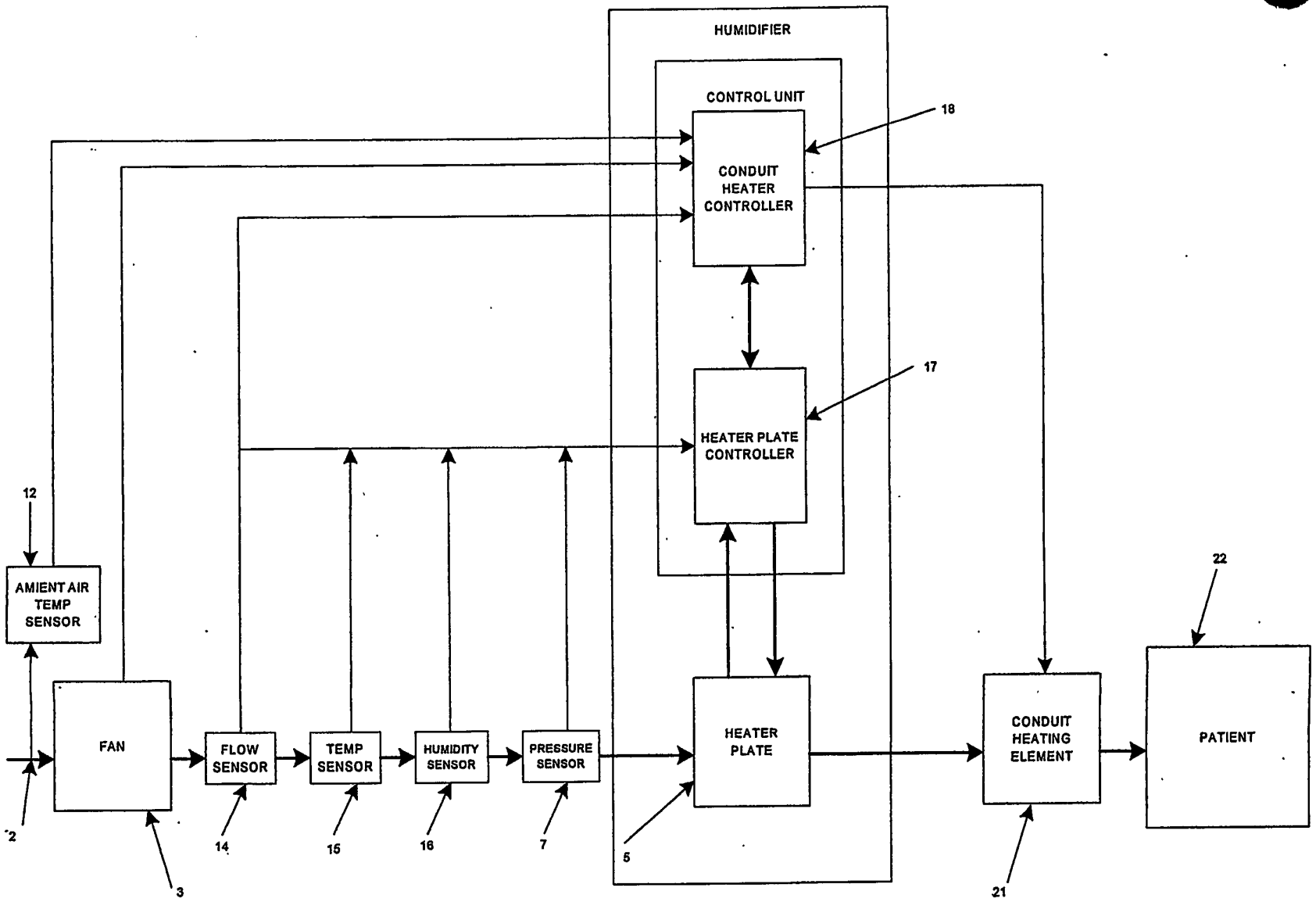
HUMIDIFIER
CONTROL UNIT
18
CONDUIT HEATER CONTROLLER
17
HEATER PLATE CONTROLLER
12
AMIENT AIR TEMP SENSOR
FAN
FLOW SENSOR
TEMP SENSOR
HUMIDITY SENSOR
PRESSURE SENSOR
HEATER PLATE
CONDUIT HEATING ELEMENT
22
PATIENT
2
3
14
15
16
7
5
21

Figure 2

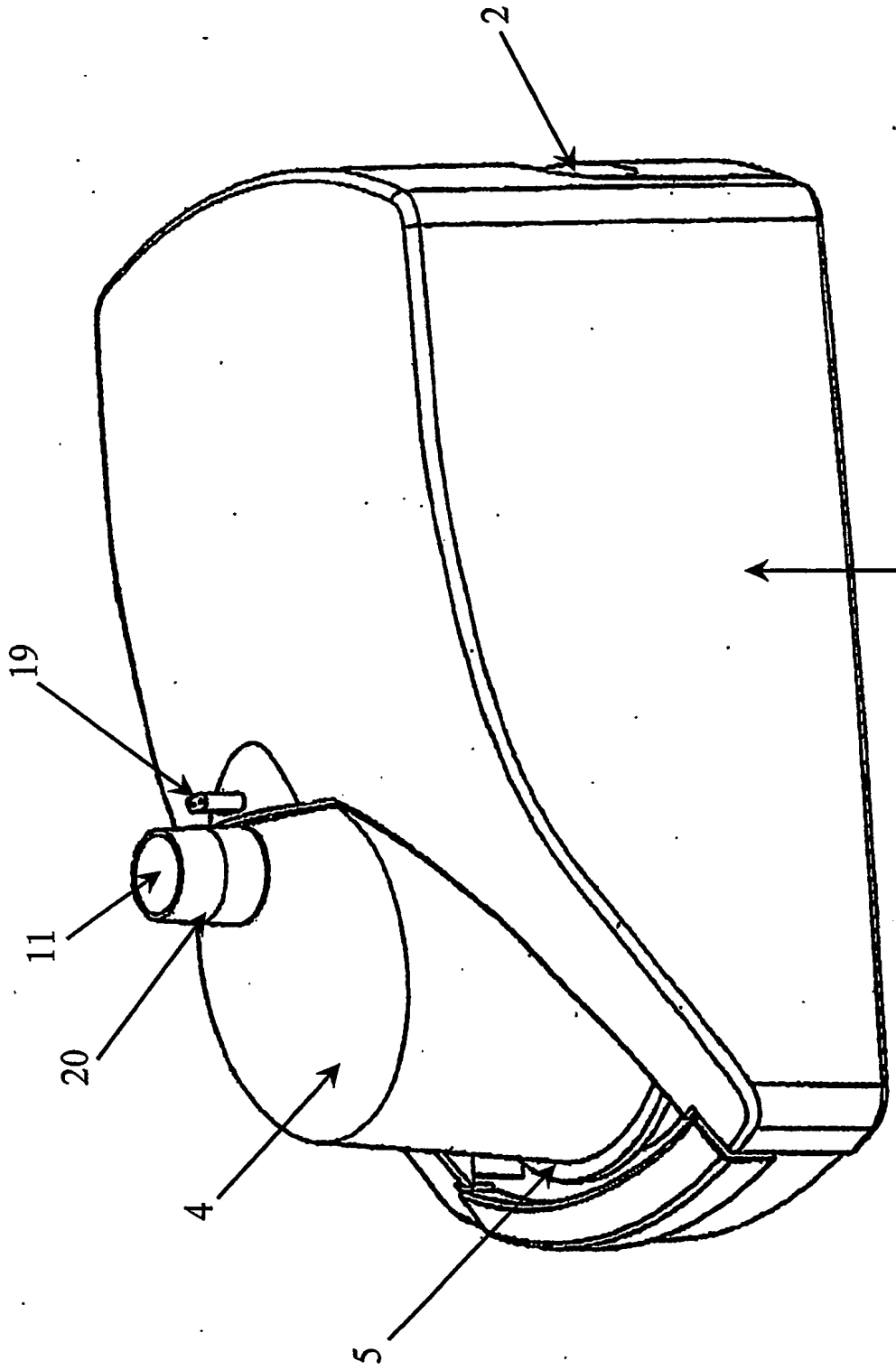

Figure 4